

## STATEMENT OF PURPOSE

The aim of the study is to assess the effect of intranasal salmon calcitonin on patients with charcot neuroarthropathy in addition to the standard of care treatment of offloading and immobilization.

## METHODOLOGY & PROCEDURES

A retrospective clinical study was conducted to evaluate the effect of intranasal salmon calcitonin as an adjunctive treatment for Charcot Neuroarthropathy. All patients were immobilized and offloaded per standard of care. Patients' temperature difference between affected and unaffected lower extremities were then measured with an infrared thermometer at each office visit. Our results were then compared to those of Bem et al's study.

13 total patients were included in our study who reached  $<2^{\circ}\text{C}$  temperature difference; we compared time of maximum temperature decrease and overall temperature decrease rates to those in Bem et al.

The sample size required for the Bem et al's study was 32 patients, which gave a power of 80% to detect a difference of 15% between the intervention and control groups with a two-sided  $\alpha$  of 0.05.<sup>1</sup>

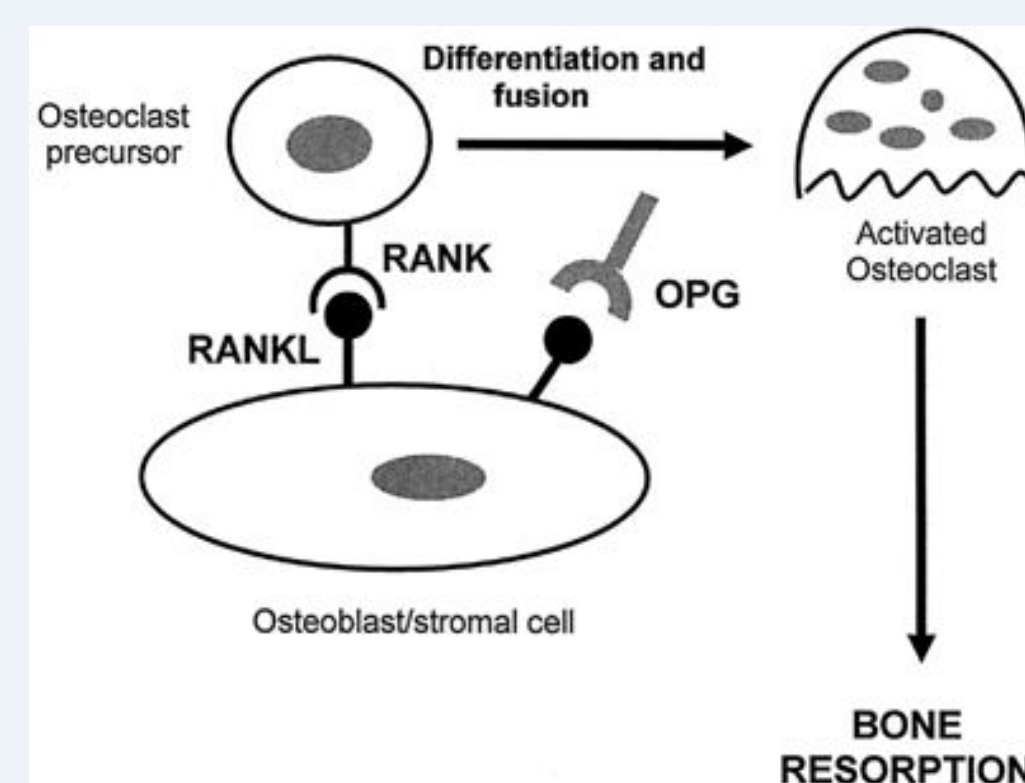
## LITERATURE REVIEW

Charcot neuroarthropathy is a complex condition with consequently various treatment options however no definitive treatment algorithm.

The standard of care for this process has been offloading and decreased or non-weight-bearing.<sup>2</sup> In addition to the neurovascular and neurotraumatic theories, increased osteoclastic activity has been proposed as a contributing factor in the destruction of bone associated with Charcot.<sup>3</sup>

Bisphosphonates have been shown to have potential positive effect on bone turnover in patients with Charcot neuroarthropathy, however they are contraindicated in patients with kidney disease and may decrease bone remodeling.<sup>4-6</sup>

Intranasal salmon calcitonin has been considered for its use in osteopenia associated with Charcot neuropathy due to its potential effect on the RANK-L/OPG pathway. It has been proposed that there is an unregulated inflammatory process in patients with Charcot neuropathy that leads to an increase in RANK-L.<sup>7</sup>



## RESULTS

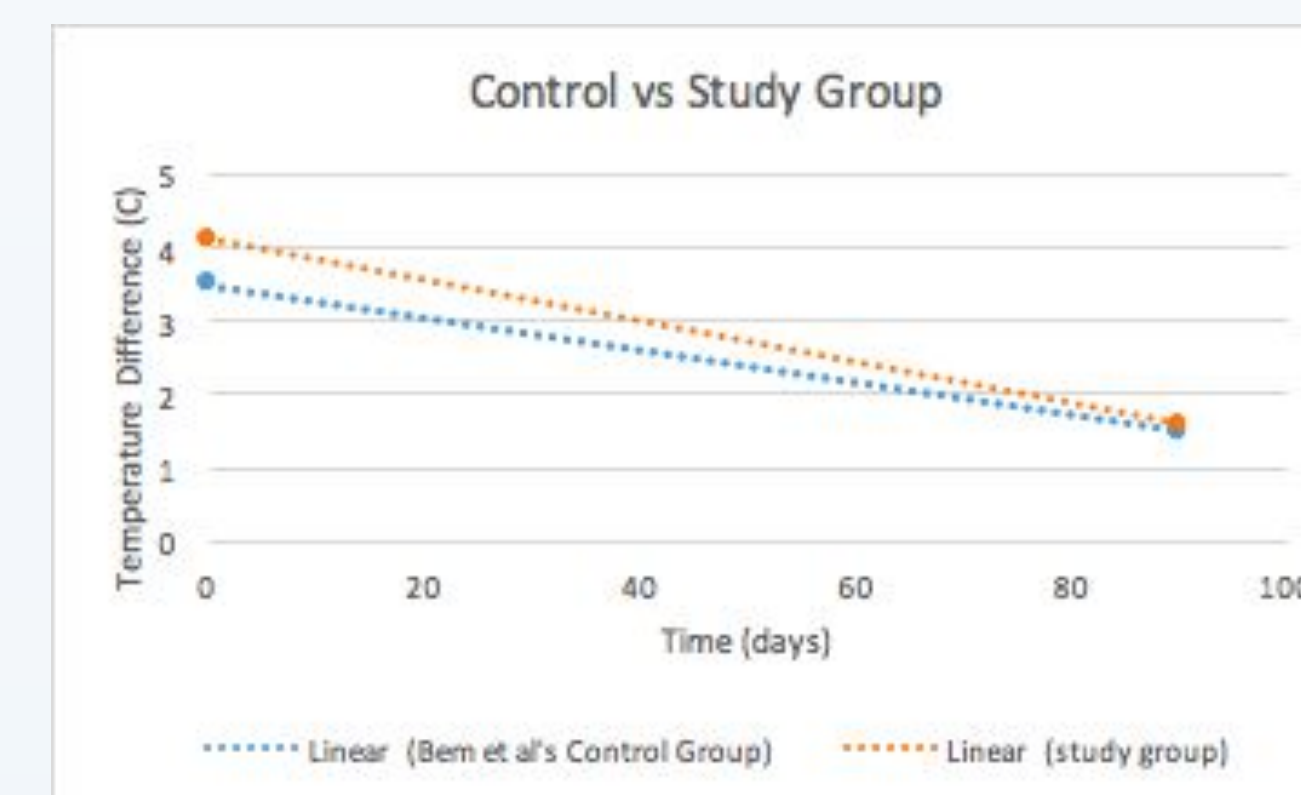
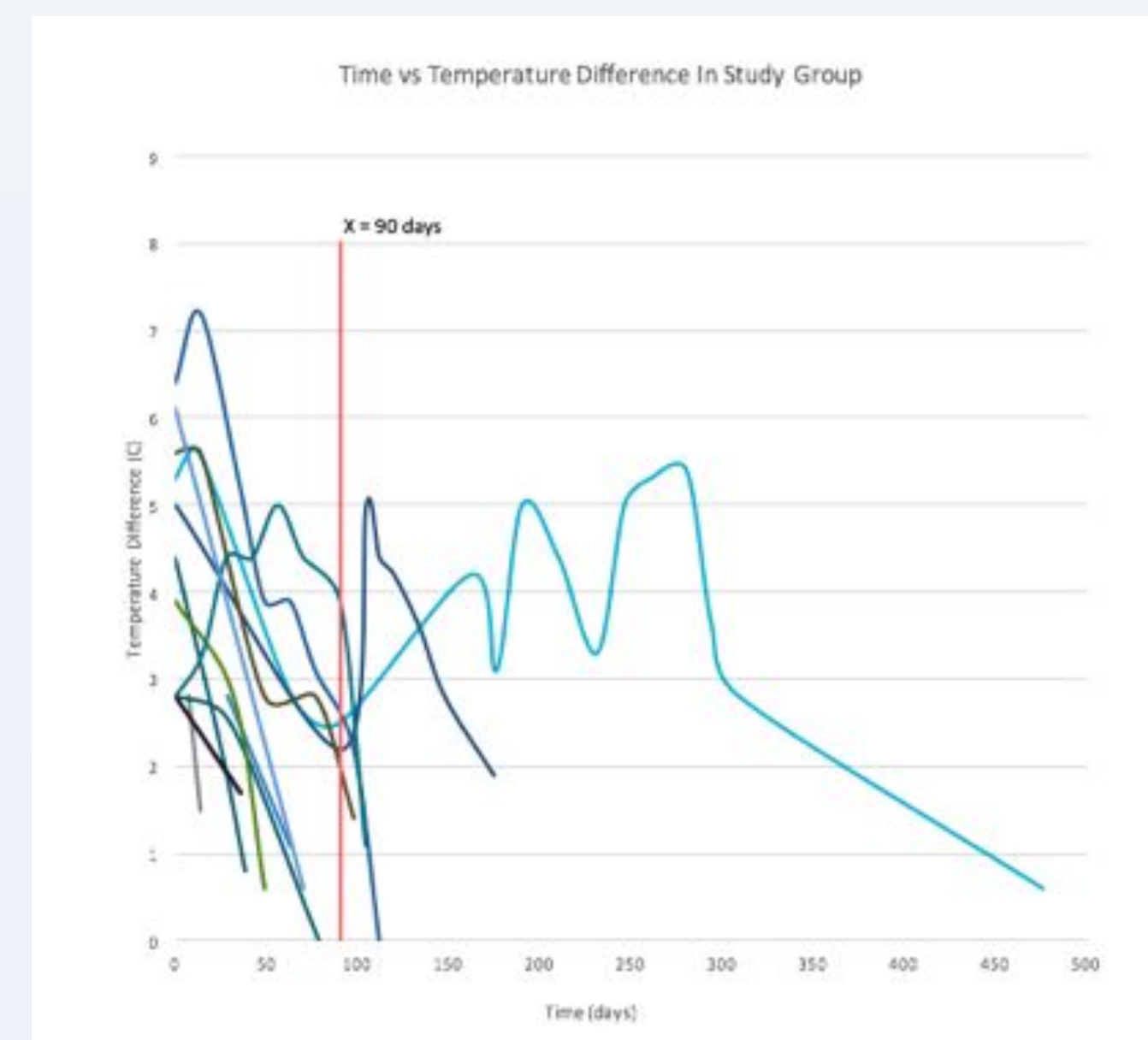
The average amount of time it took for our patients to reach  $<2^{\circ}\text{C}$  temperature difference in our study was 103.7 days, as compared to Bem et al's study who reached  $<2^{\circ}\text{C}$  temperature difference at 90 days.

In our study, subjects had a temperature difference of  $1.6 \pm 0.4^{\circ}\text{C}$  whereas subjects in Bem et al's study had a temperature difference of  $1.5 \pm 0.5^{\circ}\text{C}$ .

Initial skin temperature difference for our study was  $4.1 \pm 1.4^{\circ}\text{C}$ , and  $3.6 \pm 0.8^{\circ}\text{C}$  for Bem et al's study.

Utilizing the same statistical tools as Bem et al's (power of 80% to detect a difference of 15%), the sample size required for our study would be 22.<sup>1</sup>

We are in the process of gathering more subjects, as we currently have 13 subjects.



## ANALYSIS & CONCLUSION

Intranasal salmon calcitonin has been investigated in its use for osteopenia associated with Charcot neuroarthropathy.

In our study, it was noted that subjects had similar temperature differences at 90 days ( $1.6 \pm 0.4^{\circ}\text{C}$  vs  $1.5 \pm 0.5^{\circ}\text{C}$ , our study and Bem et al's study respectively) although subjects in our study had a greater starting temperature difference.

Intranasal salmon calcitonin may be an effective adjuvant modality in preventing progression of the disease, especially in those with renal disease, although larger clinical trials will be needed to assess its role with acute charcot neuropathy.

## REFERENCES

- Bem, Robert, et al. "Intranasal Calcitonin in the Treatment of Acute Charcot Neuroosteoarthropathy: a Randomized Controlled Trial." *Http://Isrctn.org/*, June 2012, doi:10.1186/isrctn91576704.
- S., Rajbhandari, et al. "Charcot Neuroarthropathy in Diabetes Mellitus." *Diabetologia*, vol. 45, no. 8, 2002, pp. 1085-1096., doi:10.1007/s00125-002-0885-7.
- Young, M. J., et al. "Osteopenia, Neurological Dysfunction, and the Development of Charcot Neuroarthropathy." *Diabetes Care*, vol. 18, no. 1, Jan. 1995, pp. 34-38., doi:10.2337/diacare.18.1.34.
- Jude, E. B., et al. "Bisphosphonates in the Treatment of Charcot Neuroarthropathy: a Double-Blind Randomised Controlled Trial." *Diabetologia*, vol. 44, no. 11, Jan. 2001, pp. 2032-2037., doi:10.1007/s001250100008.
- Pitocco, D., et al. "Six-Month Treatment With Alendronate in Acute Charcot Neuroarthropathy: A Randomized Controlled Trial." *Diabetes Care*, vol. 28, no. 5, 2005, pp. 1214-1215., doi:10.2337/diacare.28.5.1214.
- Stepan, J J, et al. "Mechanisms of Action of Antiresorptive Therapies of Postmenopausal Osteoporosis." *Endocr Regul*, Dec. 2003.
- Kucera, Tomas, et al. "Charcot Neuropathic Arthropathy of the Foot: A Literature Review and Single-Center Experience." *Journal of Diabetes Research*, vol. 2016, 2016, pp. 1-10., doi:10.1155/2016/3207043